

REVISED

NATIONAL

TUBERCULOSIS

CONTROL

PROGRAMME

Key Facts and Concepts



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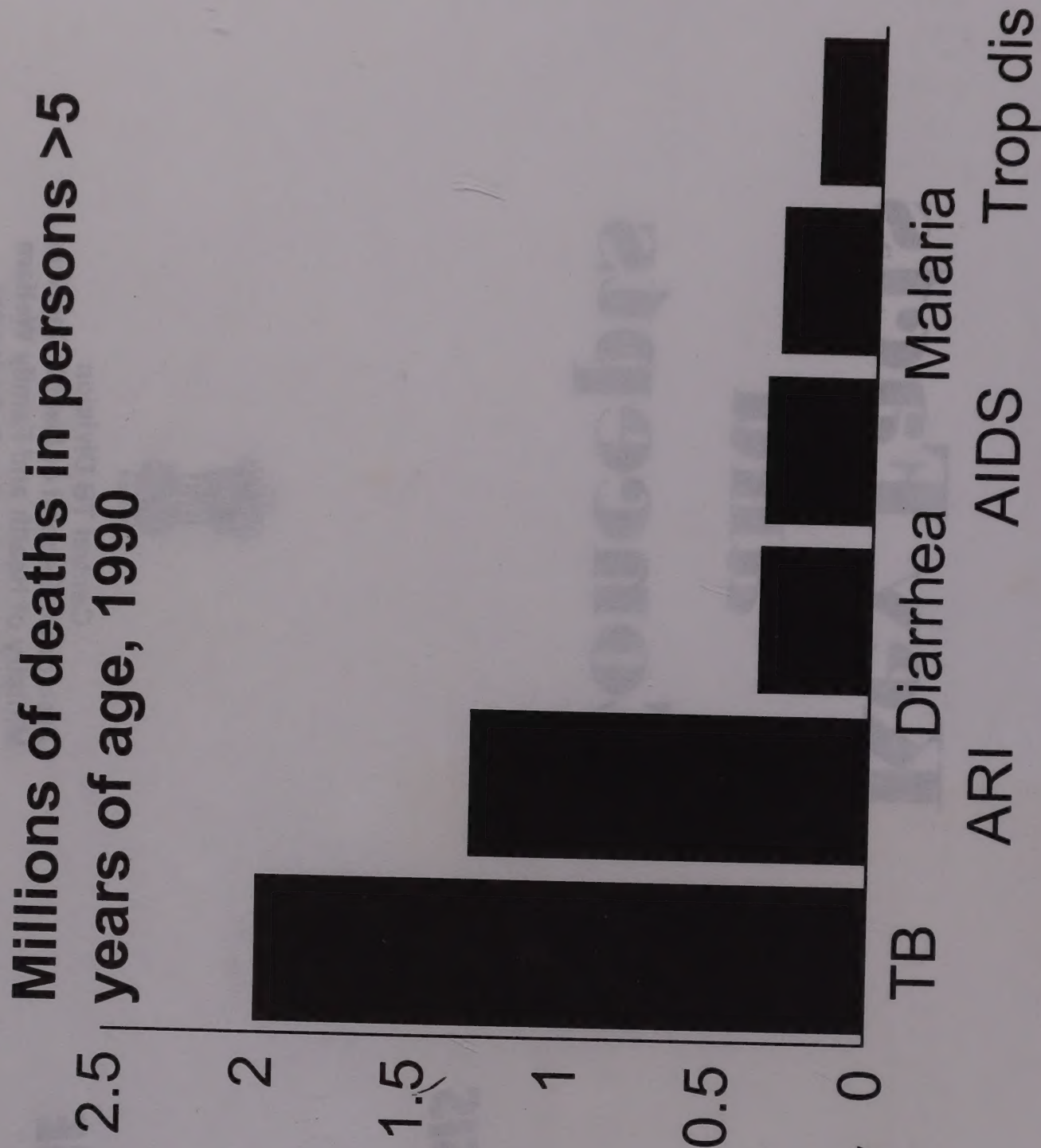
Key Facts and Concepts



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TB is a Leading Killer of Adults Globally

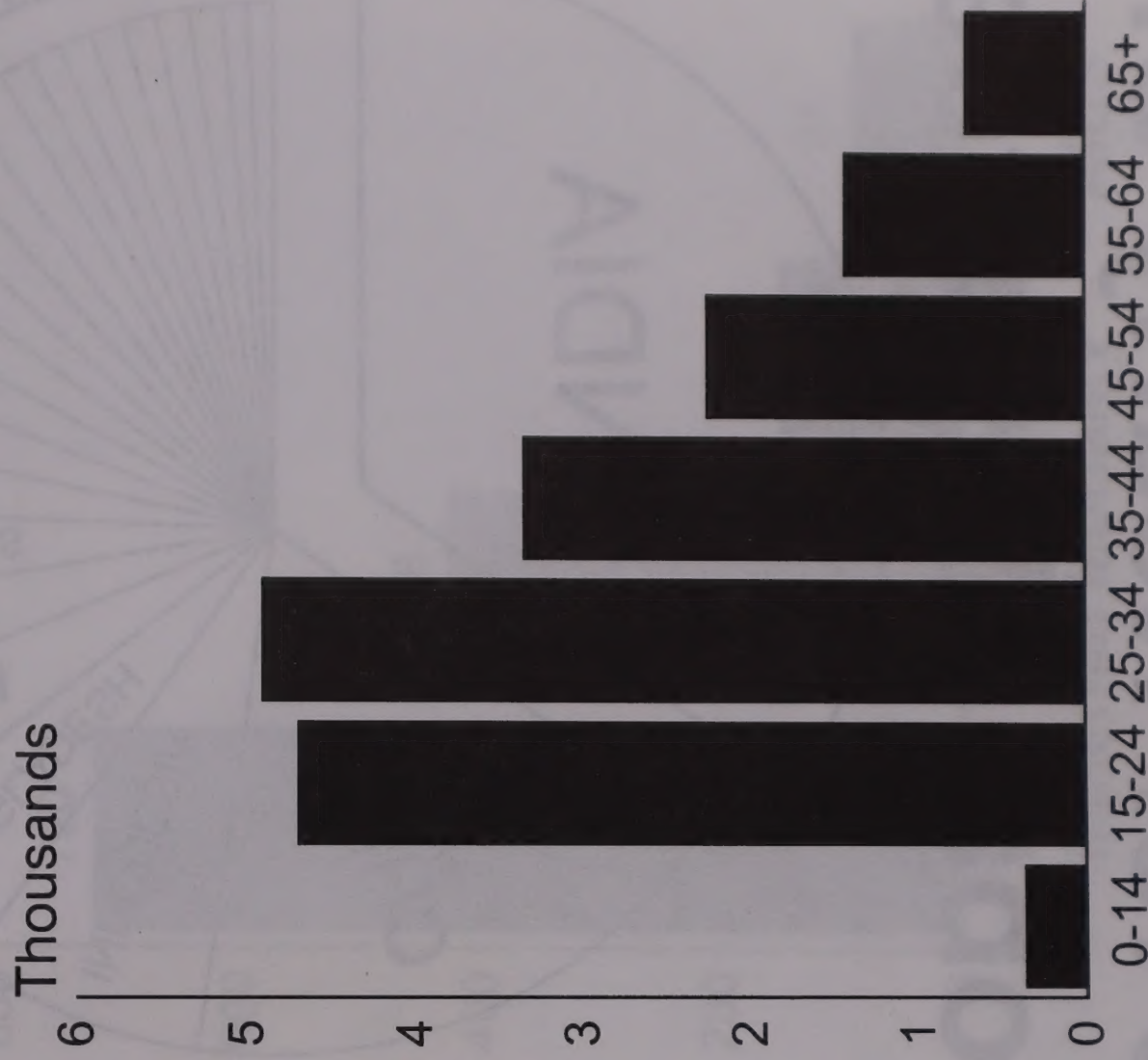
- TB kills more adults than any other infectious disease
- Because it affects adults, tuberculosis causes enormous social and economic disruption
- The burden of TB is enormous but is hidden by stigma and poor diagnostic quality



TB Affects Young Adults Most

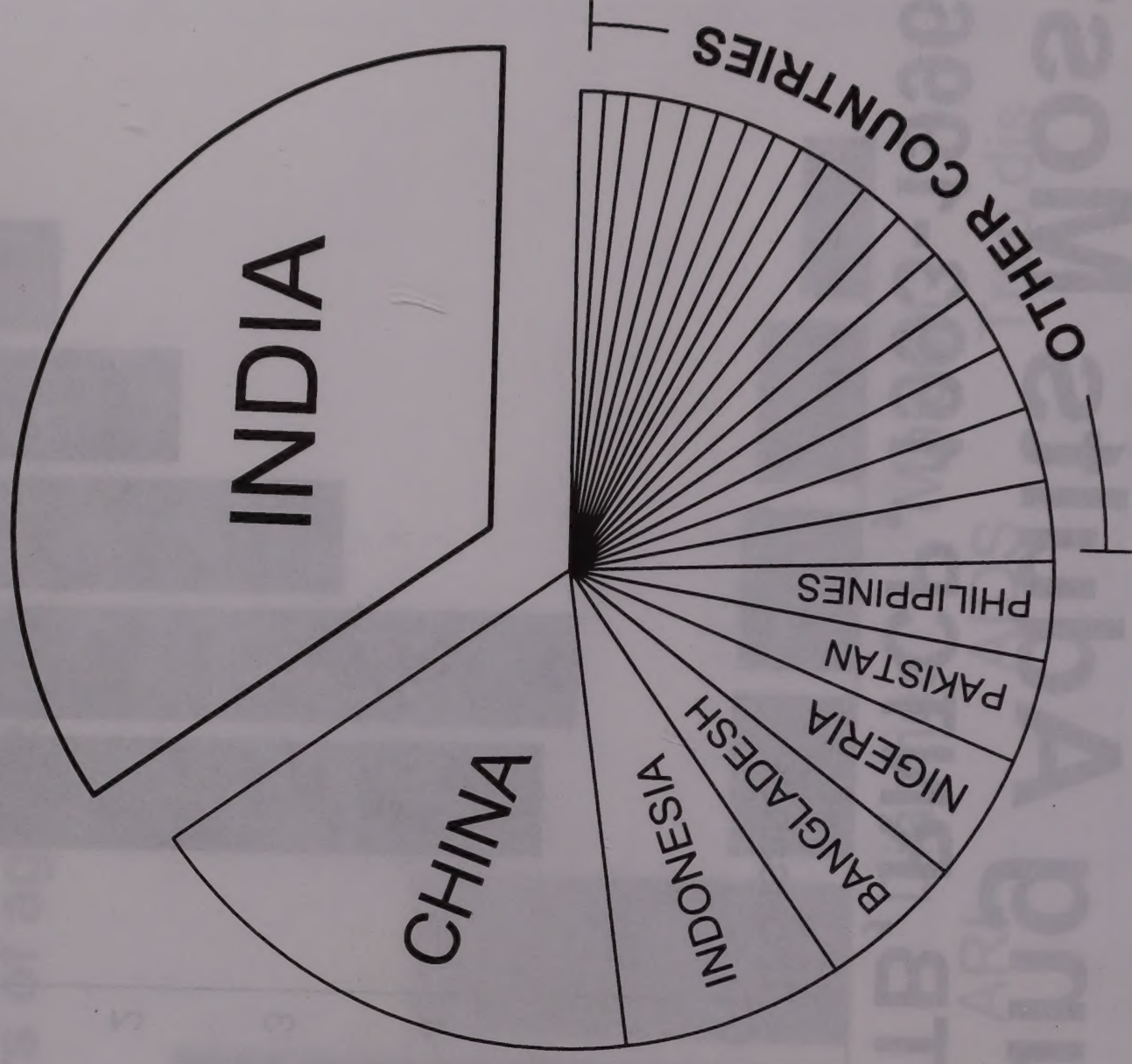
New smear-positive TB, RNTCP, 1993-1996

- TB may create more orphans than any other disease
- When districts use RNTCP formats, data on age and sex distribution of TB cases is available at each PHI, TB Unit, and District



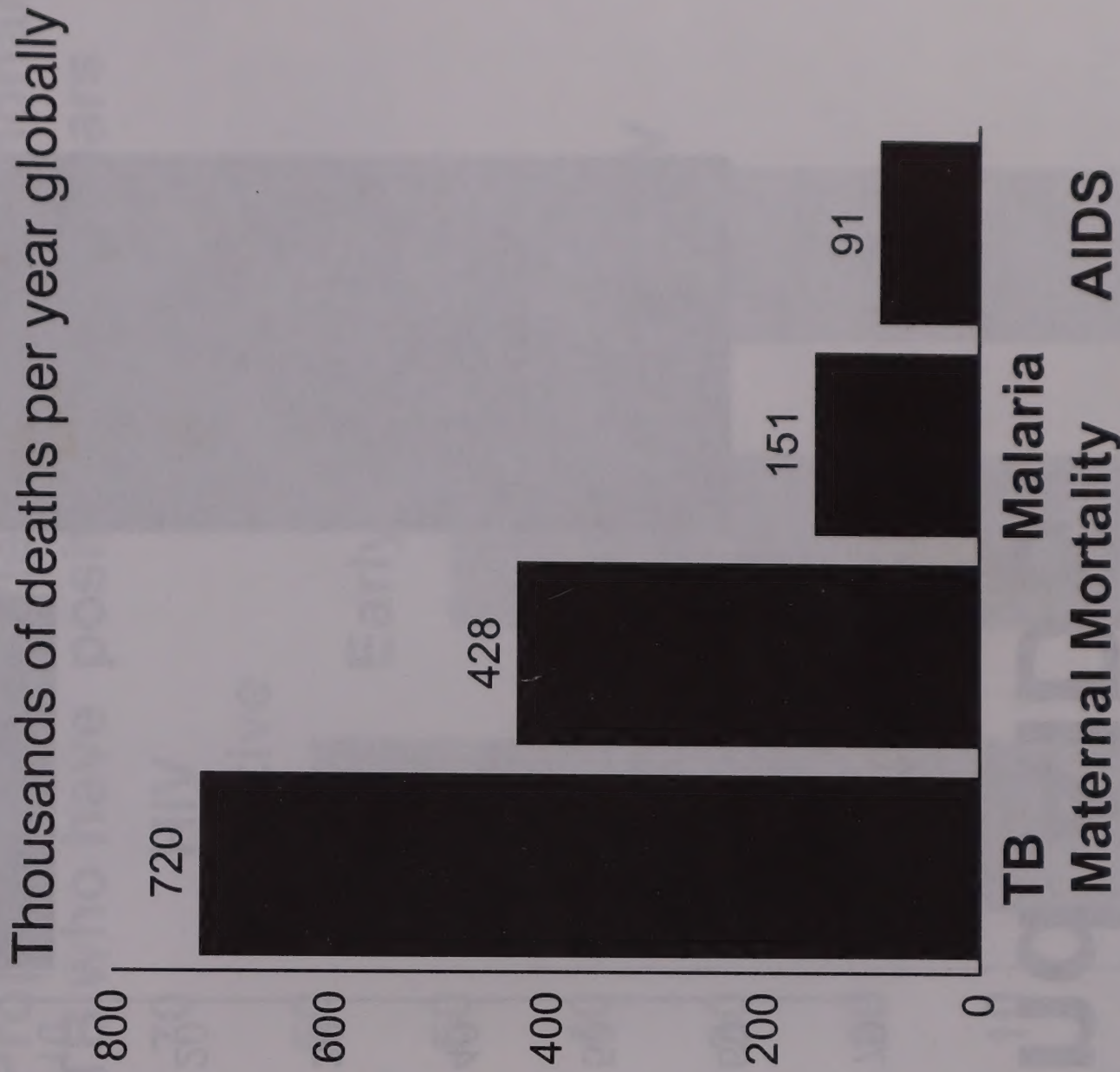
India Accounts for Nearly One Third of the Global TB Burden

- India has more cases of tuberculosis than any other country in the world and twice as many cases as China, which has the next highest number
- Although exact and current information on TB incidence and prevalence is not available, studies show an incidence rate of more than 200 per lakh, among the highest in the world



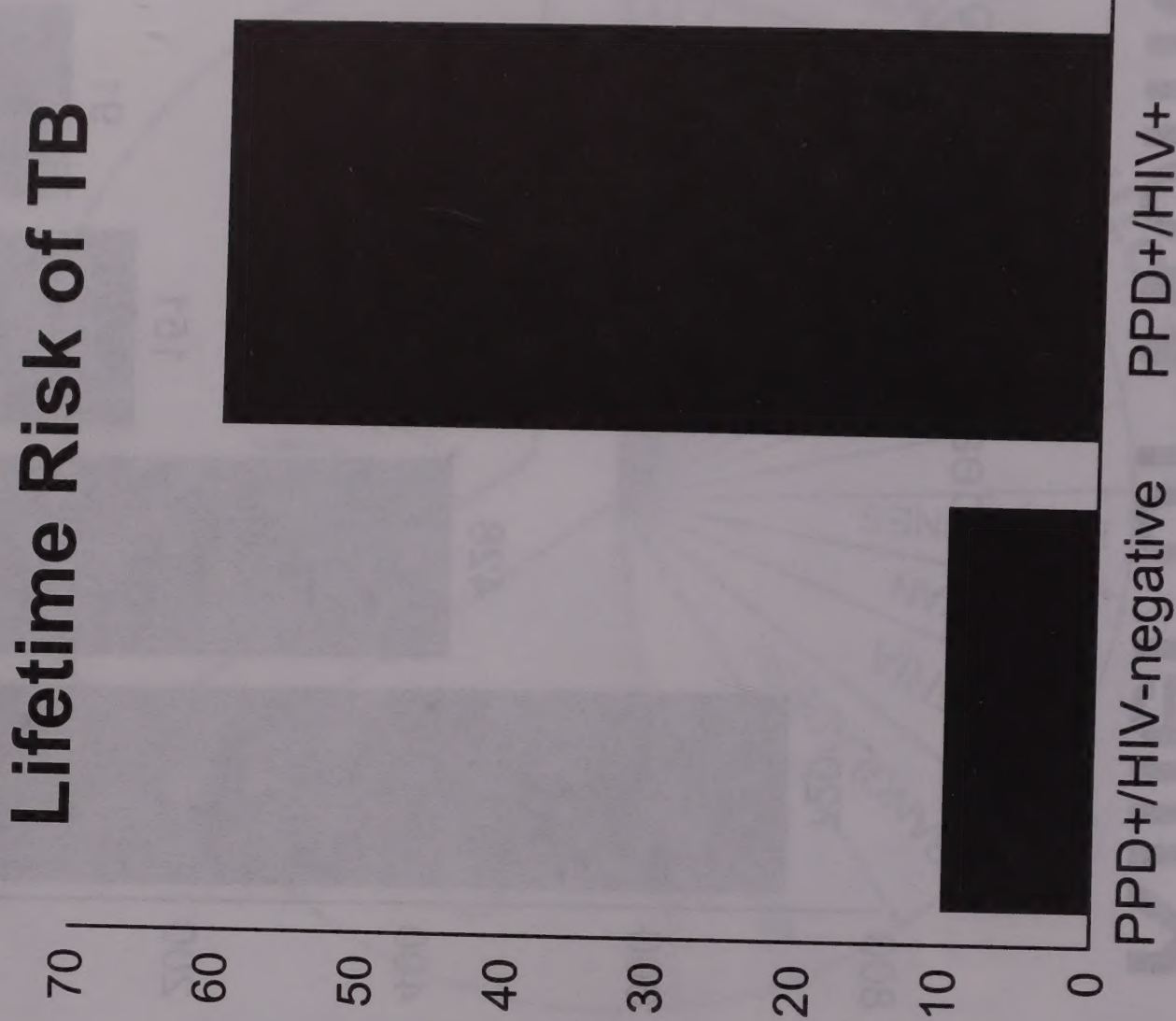
TB is a Leading Killer of Women

- TB kills more women than any other infectious disease
- TB kills more women than all causes of maternal mortality combined
- Women with tuberculosis are often severely stigmatized



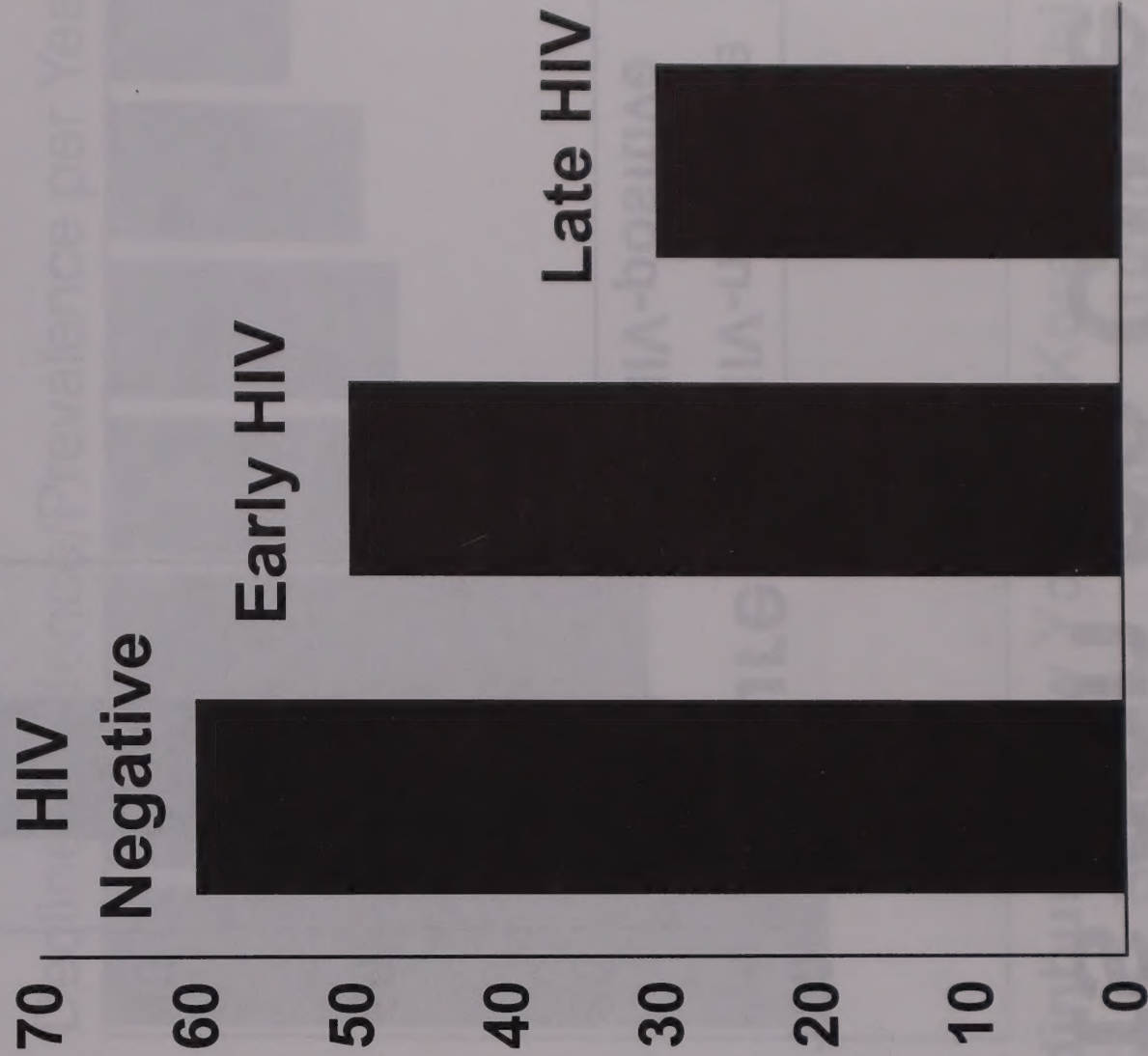
TB and AIDS

- HIV-infected persons are at greatly increased risk of TB
- Without HIV, the lifetime risk of developing TB in TB-infected people is about 10%, compared with at least 50% in HIV-infected, TB-infected people
- The HIV epidemic could rapidly increase the incidence of TB



Diagnosis of TB in HIV+ Persons

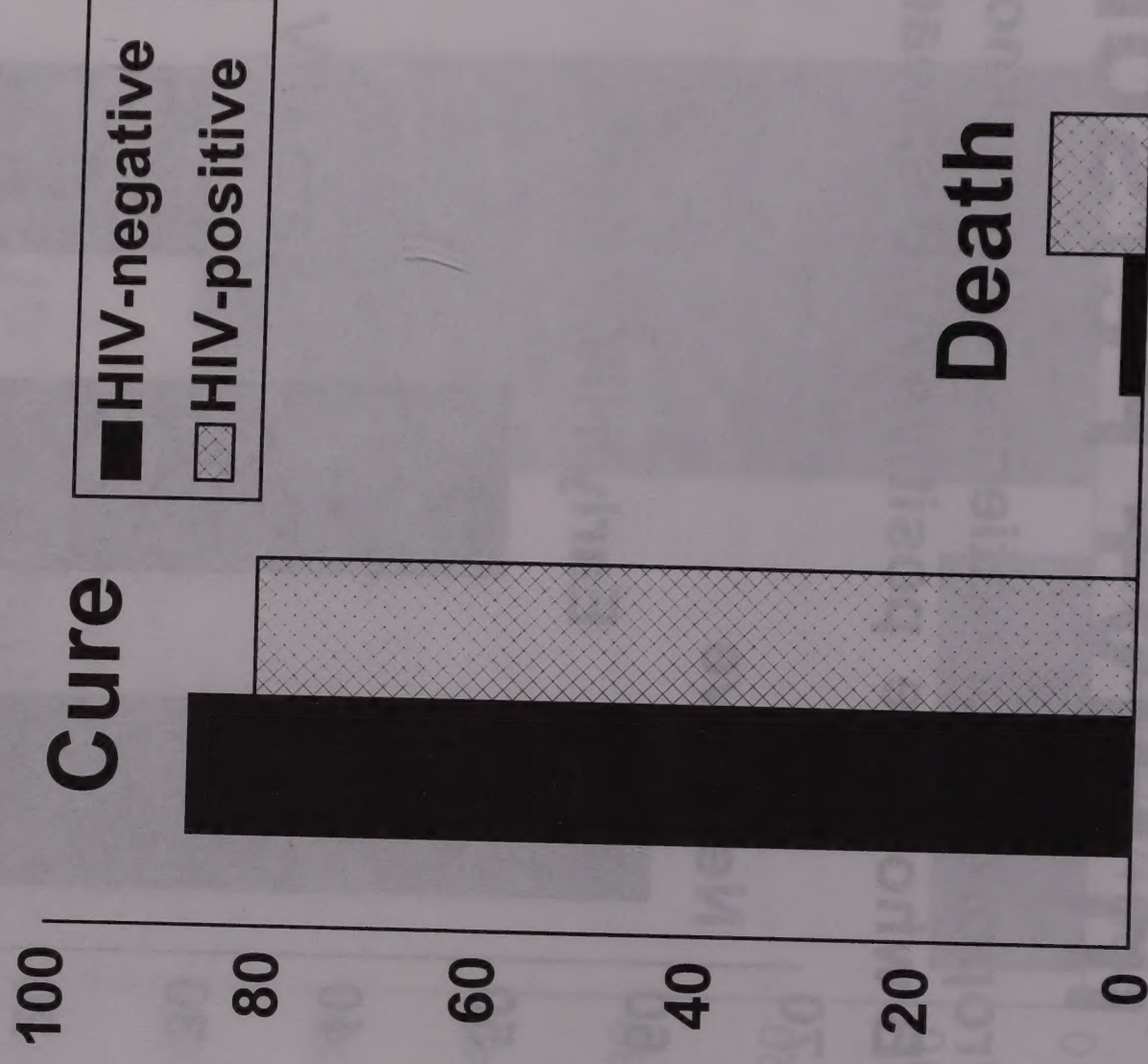
Proportion of patients with pulmonary TB who have positive AFB smears



- Diagnosis of TB in HIV-infected persons is more difficult
 - More non-TB respiratory disease
 - More smear-negative and extrapulmonary TB
 - X-rays are even less specific

HIV+ TB Patients can be Cured

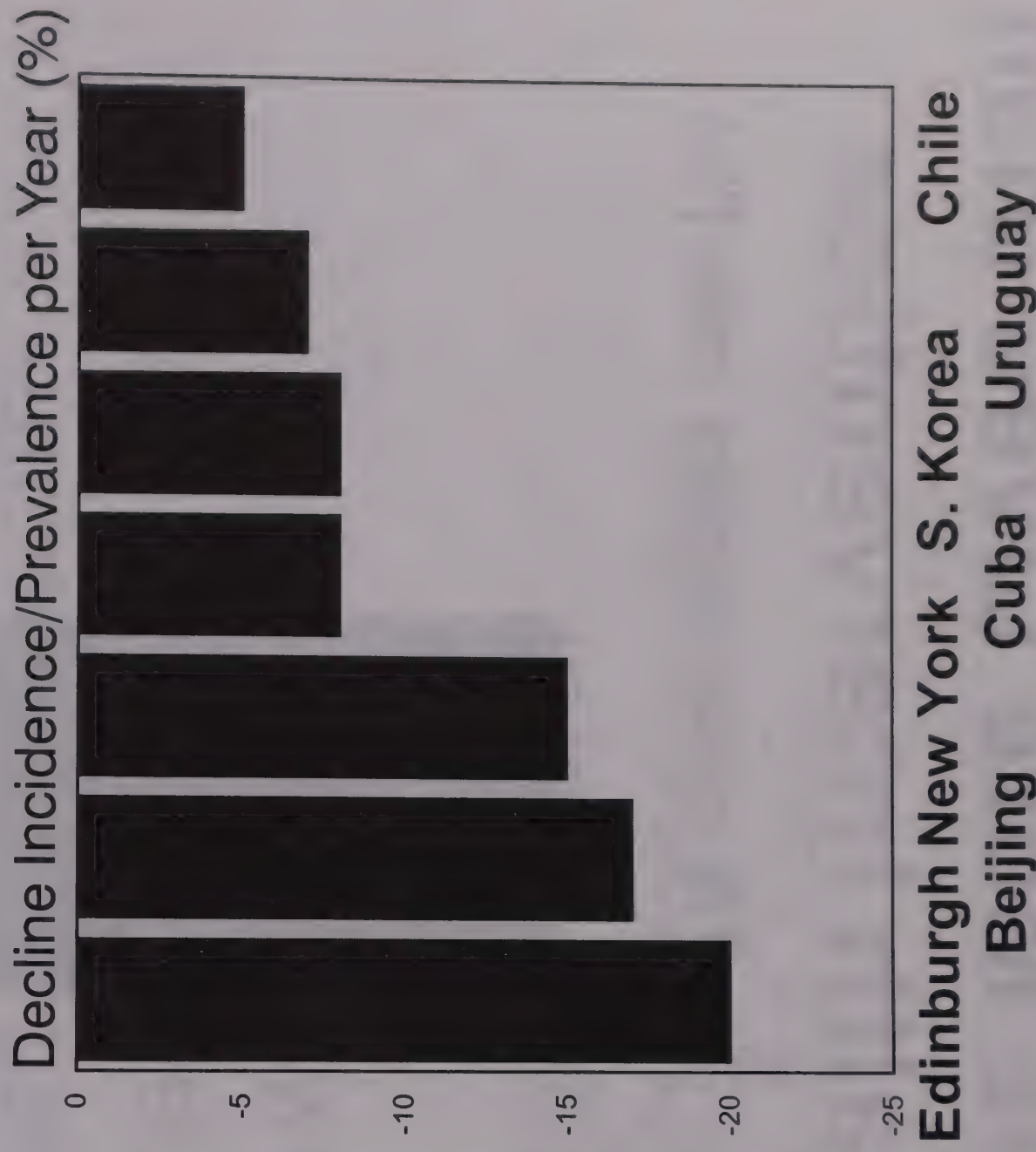
- Even among HIV-infected patients, TB can be cured
- More than 90% of surviving HIV-infected TB patients can be cured of TB
- Overall TB cure rates are slightly lower among HIV-infected patients, because of deaths from non-TB causes



Chaisson, ARJCCM, 1996

TB Can be Cured and the TB Epidemic Reversed

- Modern treatment can cure nearly all patients -- if it is taken for a full course under direct observation
- In areas where effective diagnosis and treatment has been implemented, cases have decreased by 5-20% per year
- An effective control programme can significantly reduce incidence of TB

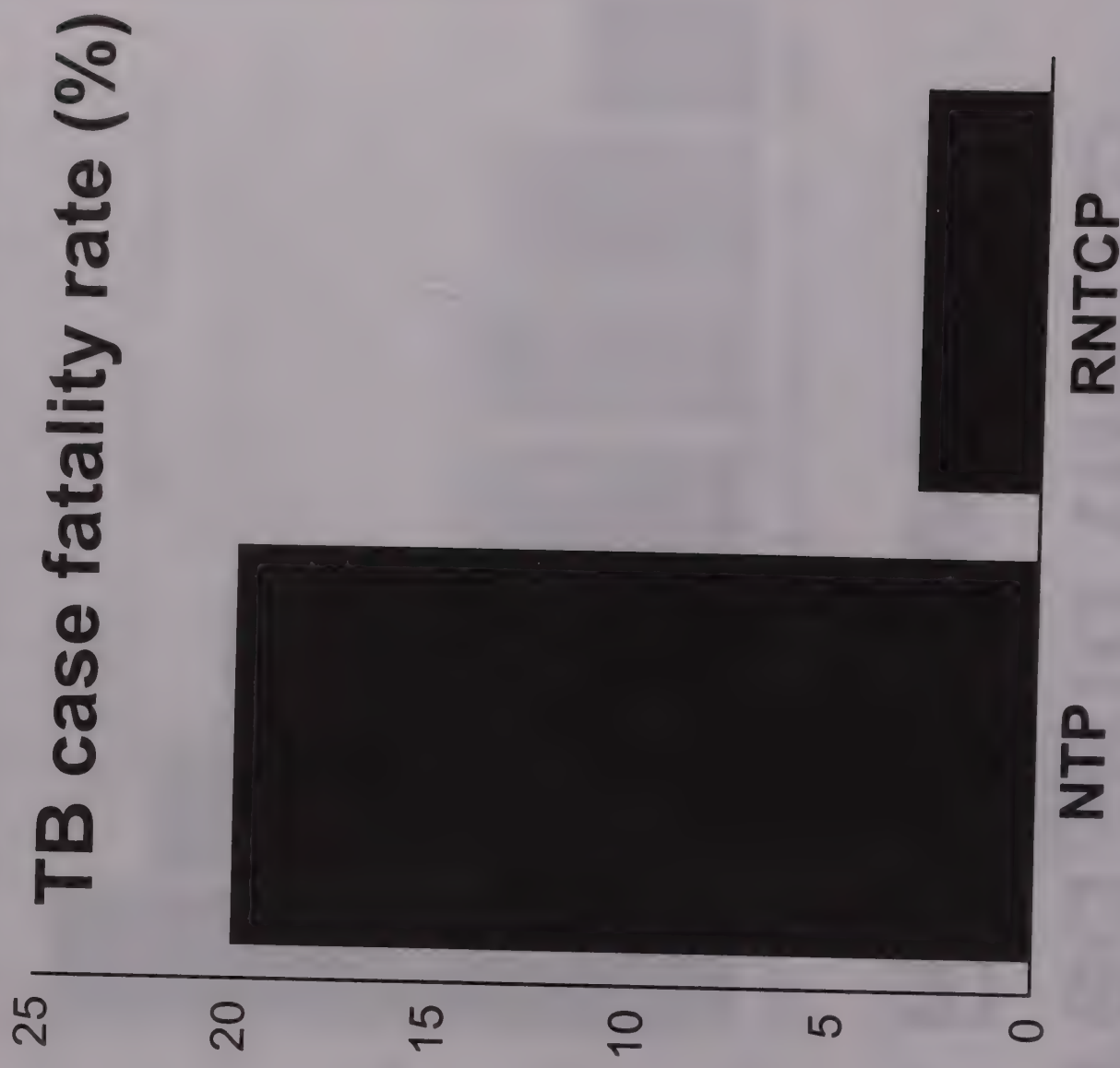


RNTCP Can Save More Lives than Any Other Health Intervention

- An estimated 5,00,000 people die from TB in India every year -- more than 1,000 every day, 1 every minute

- Most of these deaths could be prevented by effective tuberculosis control

- Case fatality in the NTP is more than 3-10 times higher than that of RNTCP



"The DOTS strategy represents the most important public health breakthrough of the decade, in terms of lives which will be saved."

—Director General
World Health Organization
March 24, 1997

TB and Poverty

- TB is more common in poor and malnourished people, but spreads without regard for socio-economic status
- TB treatment is effective independent of nutritional or economic status
- Adherence to treatment is irregular, regardless of age, sex, religion, education, or severity of disease -- therefore, directly observed treatment is standard of care for all TB patients
- Access to treatment is more difficult for the poor
- Community-level treatment will ensure cure of infectious patients and reduce spread of disease

TB and Primary Health Care

- Most TB patients consult health facilities for diagnosis
 - Quality, prompt diagnosis is essential
 - No need for case finding in community
 - TB diagnosis and management are integral part of PHC
- Important reasons for stopping treatment include poor access, inadequate care, and irregular drug supply
 - Treatment must be accessible
 - DOT ensures drug intake, improves care, and facilitates defaulter retrieval

TB Control: The 5 Components of DOTS

- Political commitment
- Diagnosis by microscopy
- Adequate supply of SCC drugs
- Directly observed treatment
- Accountability



Exercise 1: How Important is RNTCP?

Estimated TB mortality rate in India: 53/lakh. Proportion of deaths among 18-59 years: 80%.

Population of your area: _____ lakh

Estimated deaths from TB per year: _____ per month: _____ per week: _____

Estimated deaths from TB per year among 18-59 year olds: _____

Assuming economic productivity of, on average, Rs 10,000 per year per person, and average remaining workspan of 20 years, annual loss in productivity from TB deaths in your area: _____ deaths X 20 years X Rs 10,000/year = _____

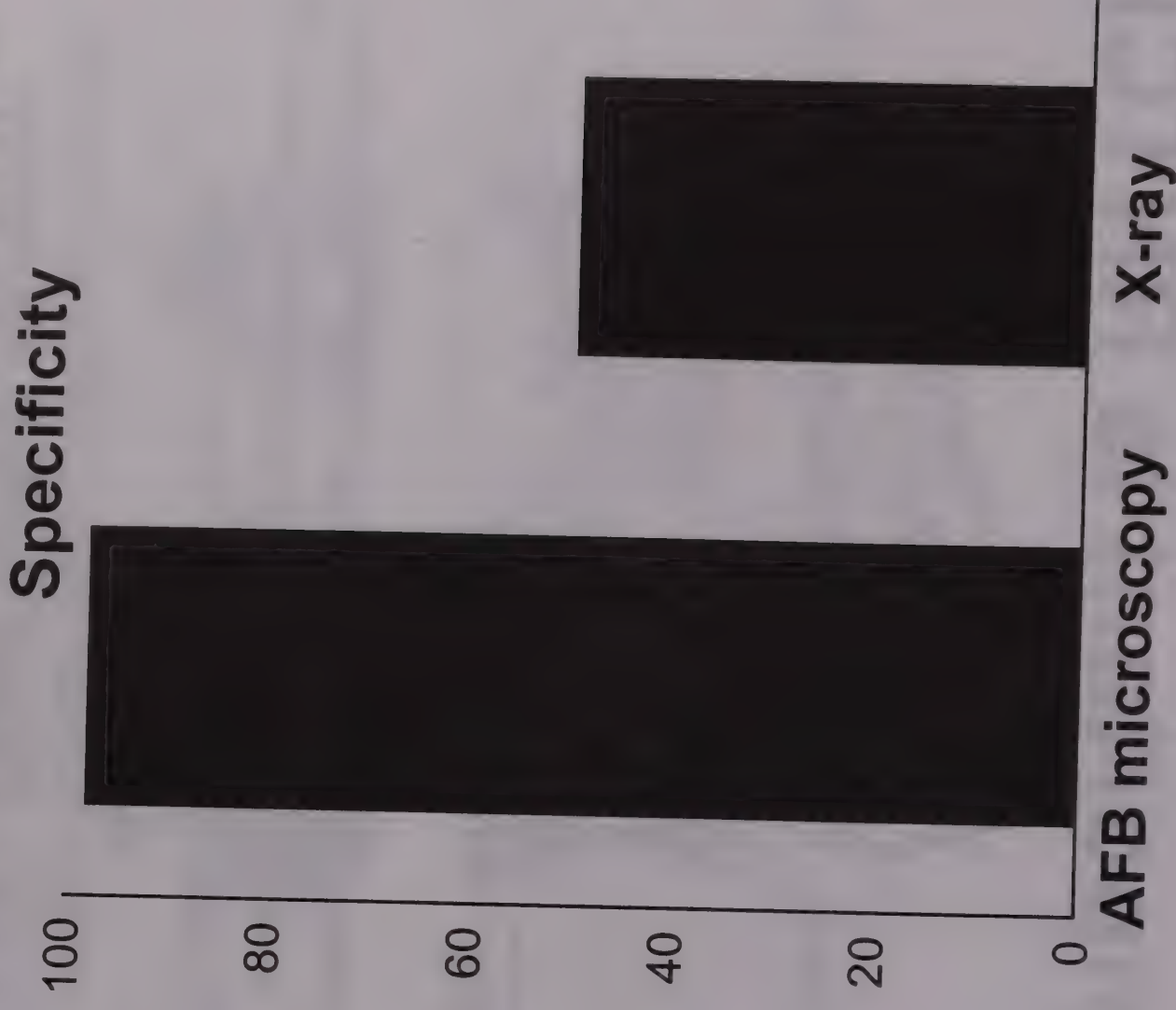
RNTCP implementation reduces death rate by at least half. Deaths averted per year by RNTCP implementation: _____ Economic losses averted by RNTCP implementation: _____ deaths X 20 yrs X Rs 10,000/yr = Rs _____

Diagnosis by Microscopy of Patients Presenting to Health Facilities

- Microscopy is more accurate than x-ray, and correlates with infectiousness as well as with risk of death from TB

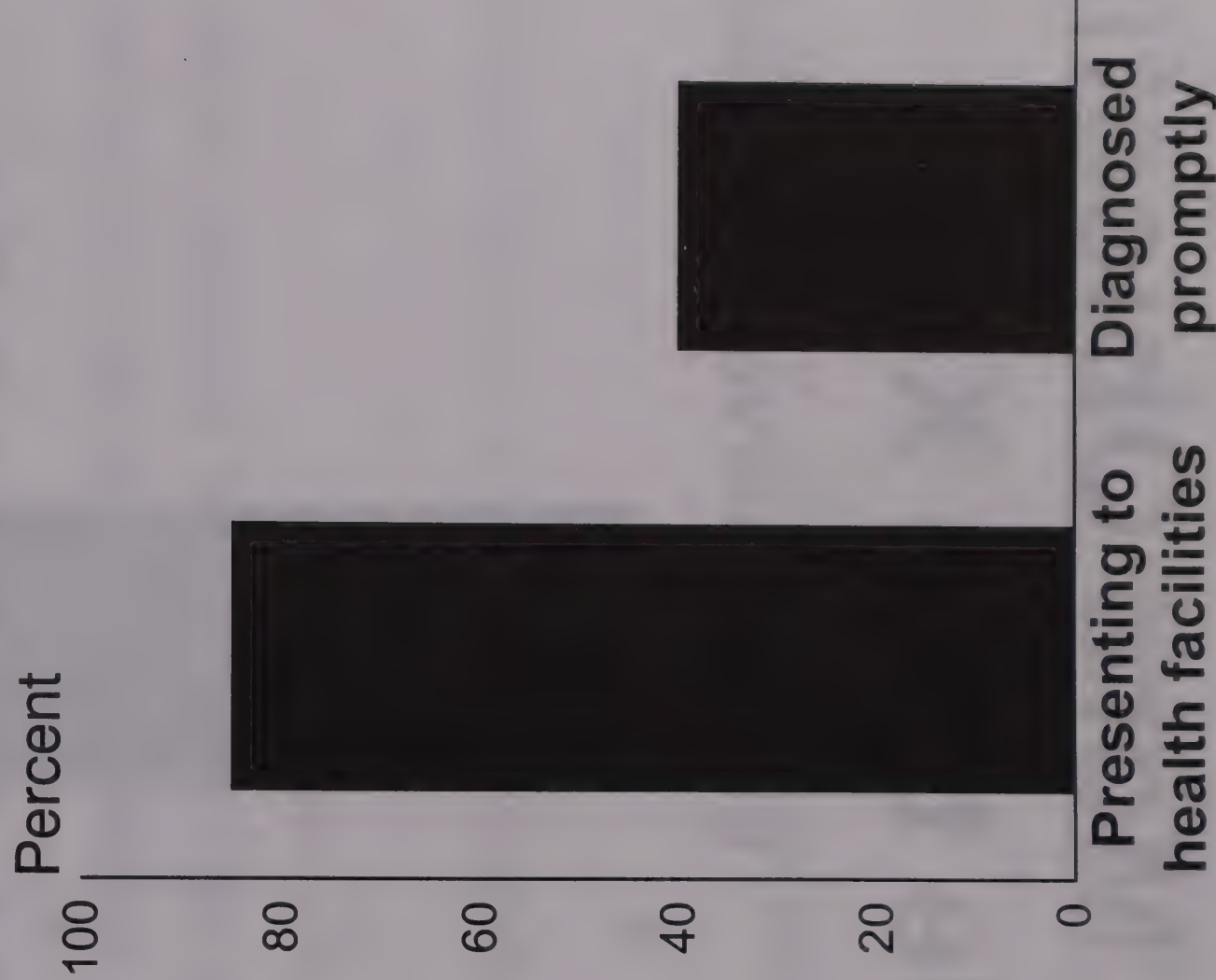
- Virtually all patients with multiple positive direct AFB smears have TB

- At least half of persons with x-rays suggestive of TB do not have TB



More than 80% of TB Patients Attend Health Facilities Promptly, but are not Diagnosed Promptly

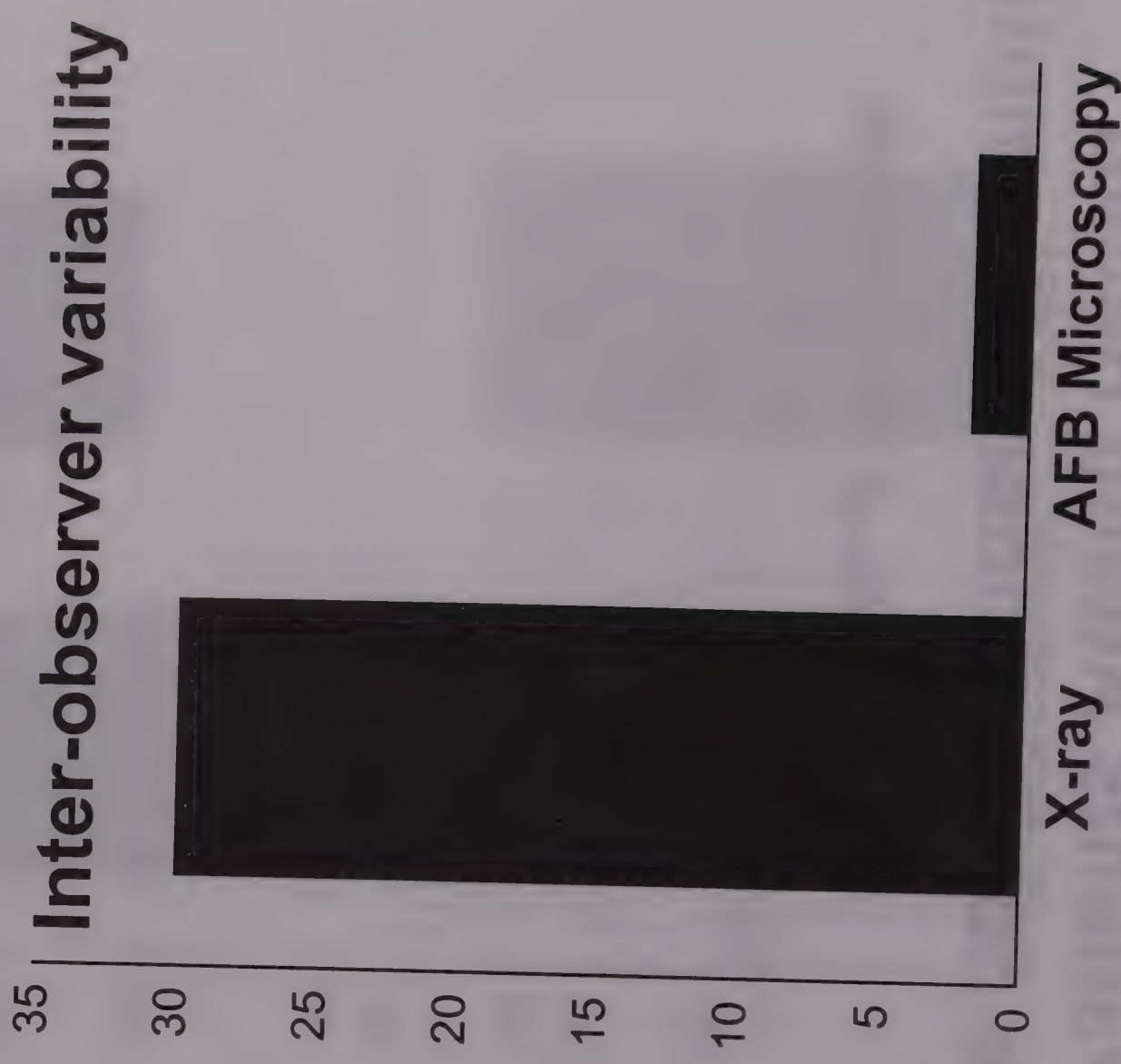
Diagnosis of TB Patients



- At least 2% of adult outpatients attending general health facilities have cough for 3 weeks or more, of whom approximately 10% will have positive smears
- Unfortunately, most patients who present to facilities with cough for more than three weeks are not sent for sputum examination
- Studies in India show that more than 80% of patients with TB attend health facilities promptly
- Active case finding in the community is both unnecessary and unproductive

Microscopy is More Objective and Reliable than X-ray

- Inter-observer variability is much less with microscopy than with x-ray



- AFB microscopy provides information on infectiousness of the patient, which x-ray does not
- AFB microscopy allows prioritization of cases, which x-ray does not
- AFB microscopy is also an objective method to follow the progress of patients on treatment

X-ray is an Important Complementary Tool

- All patients with cough of 3 weeks or more should have 3 sputa examined for AFB. If negative, they should receive 10-14 days of broad-spectrum antibiotics
- If symptoms persist after the above, then X-ray should be taken
- X-ray findings should always be interpreted along with clinical judgement
- X-ray is essential for the diagnosis of smear-negative TB and some forms of extra-pulmonary TB

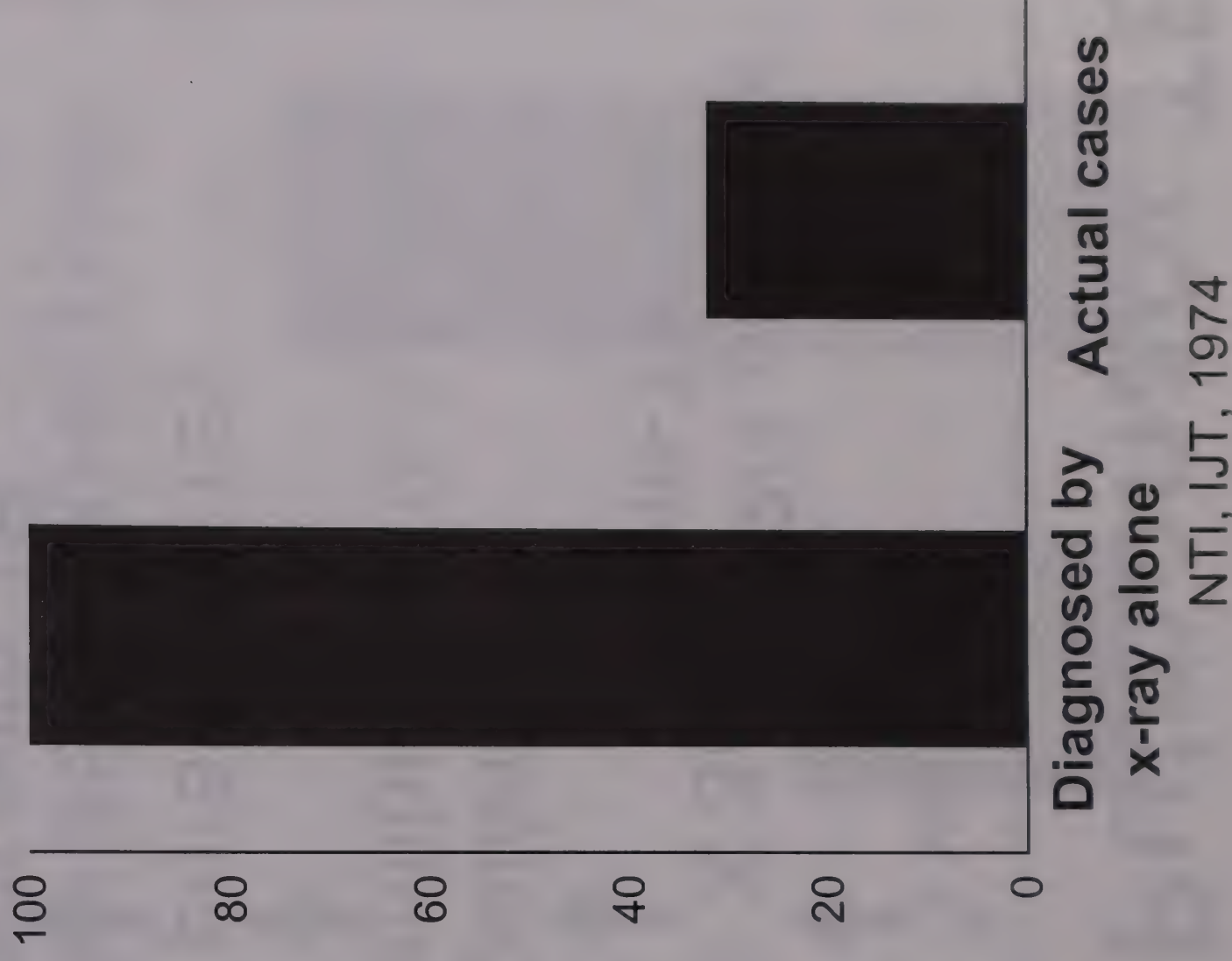
Problems with Over-Reliance on X-ray for TB Diagnosis

- Misclassification of non-TB as TB, resulting in unwarranted treatment and avoidable expenditure
- Inability to distinguish between smear+ and smear-negative patients, resulting in inadequate priority to true smear+ patients
- Failure to give appropriate treatment
- Inability to monitor progress accurately
- Lower cure rates and increased spread of TB

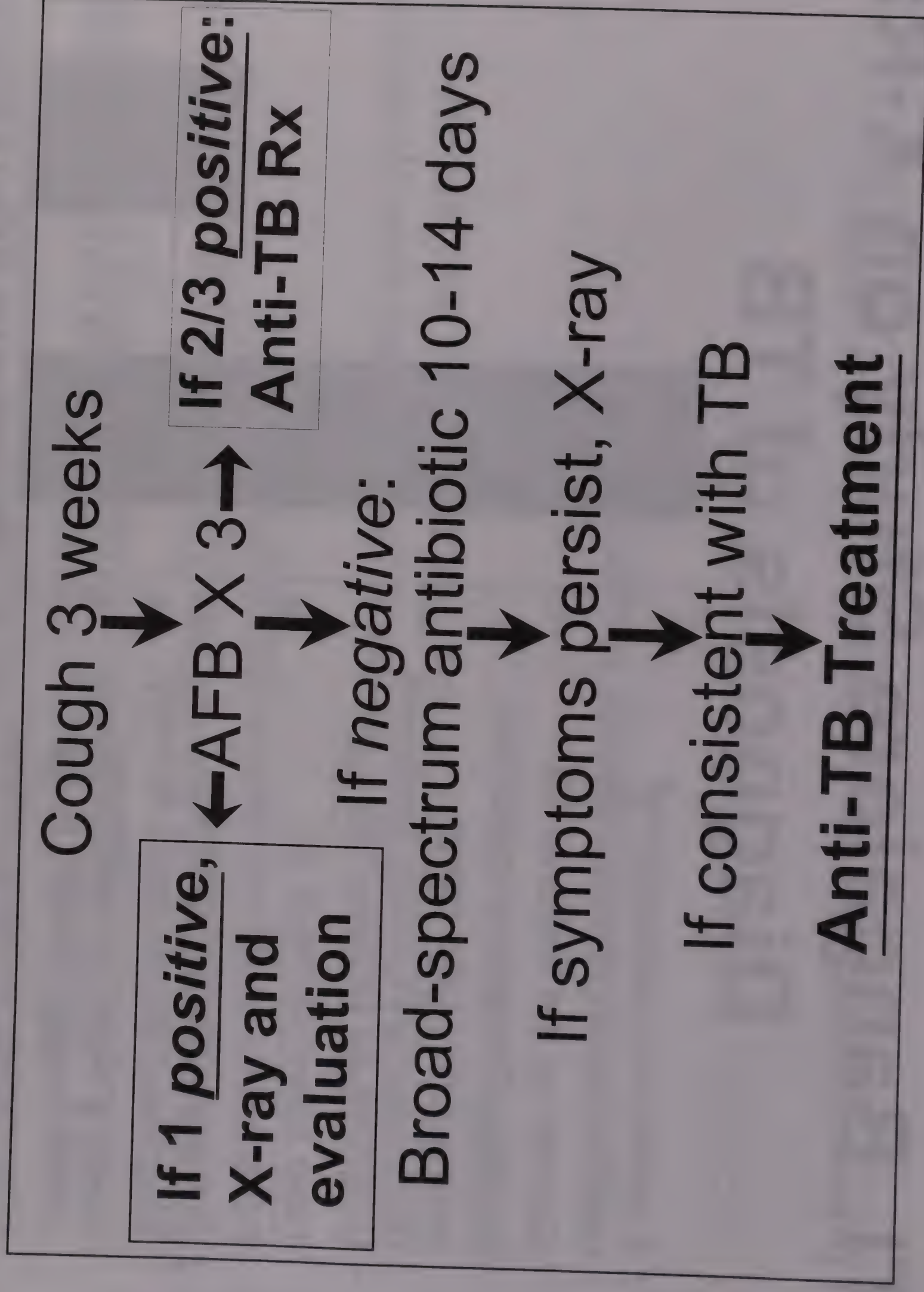
NTI, Bangalore Study on X-Ray

Diagnosis of TB

- A systematic evaluation of well-functioning District TB Centres by the National TB Institute, Bangalore found that nearly 70% of the cases diagnosed and put on treatment on the basis of x-ray, did not have tuberculosis at all
- The proportion of cases diagnosed on the basis of x-ray alone and put on treatment unnecessarily is likely to be even higher in many centres



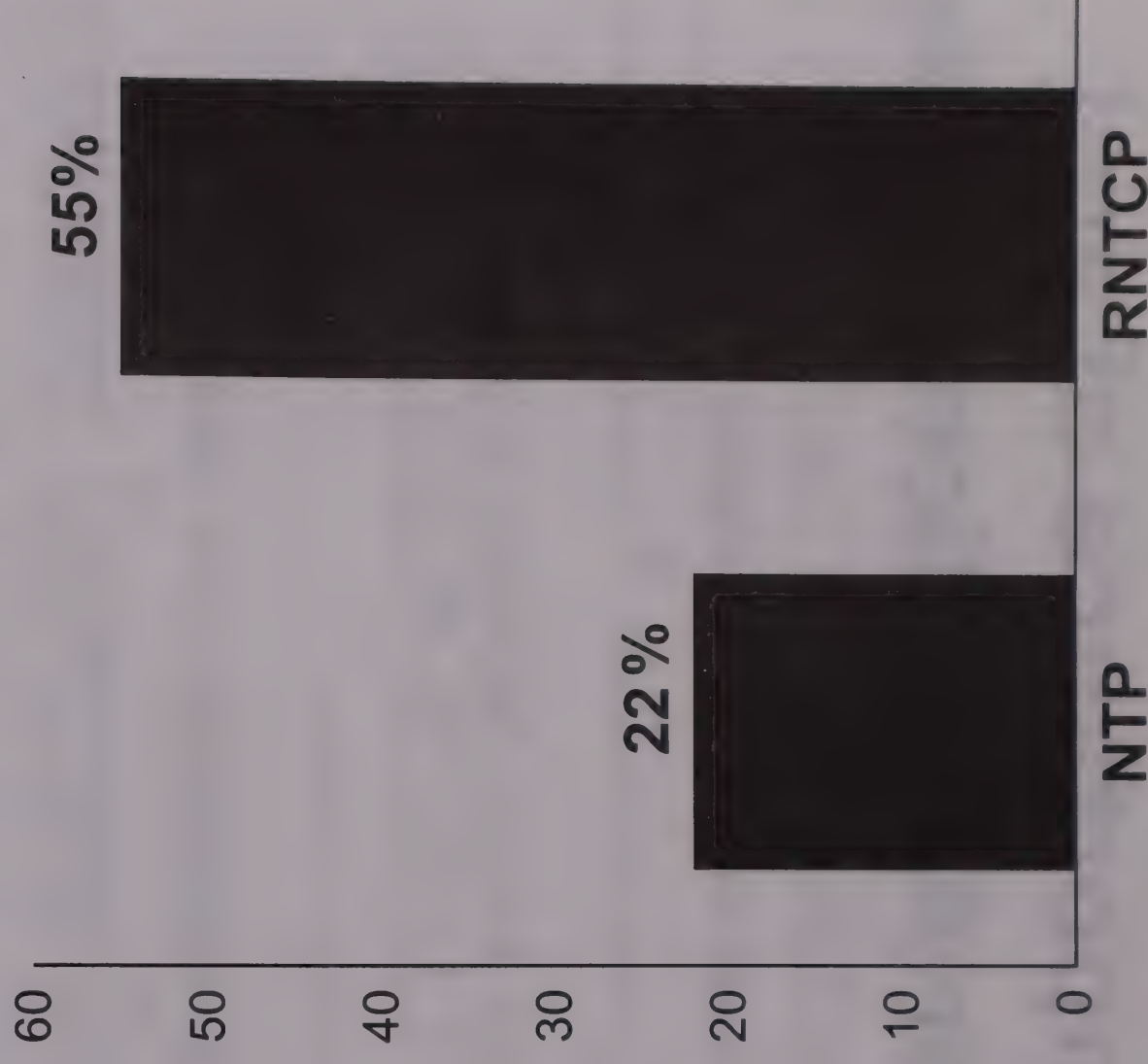
Diagnosis of Pulmonary TB



In a Well-Functioning Program, More than Half of Pulmonary TB Cases are Smear-Positive

- In NTP, only one in five pulmonary cases have positive smears documented

- In RNTCP, more than half of pulmonary cases have positive smears documented



Exercise 2: Importance of and Requirements for AFB Microscopy

List 5 advantages of microscopy for diagnosis of tuberculosis: 1. _____
2. _____ 3. _____ 4. _____ 5. _____

List 5 disadvantages of x-ray as primary tool for diagnosis of tuberculosis:
1. _____ 2. _____ 3. _____ 4. _____
5. _____

List 5 inputs which must be present for microscopy to be effective:
1. _____ 2. _____ 3. _____ 4. _____
5. _____

List 5 adverse health consequences which may arise if continuous staffing of a well-trained laboratory technician at a microscopy centre is not ensured:
1. _____ 2. _____ 3. _____
4. _____ 5. _____

Uninterrupted Supply of SCC Drugs

- In RNTCP, drugs supplied in patientwise boxes -- no patient will ever begin treatment unless full course is available
- Buffer stocks of drugs held at MSD, district, and subdistrict levels
- Quarterly reporting allows close monitoring of drug stocks and replenishment of drug supply as needed

RNTCP Treatment Regimens are Scientifically Proven and Highly Effective

- Standardized intermittent short-course chemotherapy provides more than 95% relapse-free cure
- Cure rates are equally high among patients with severe, cavitative disease
- Treatment is according to type of patient (new vs previously treated), severity of illness, and objective response to treatment (follow-up sputum examinations)

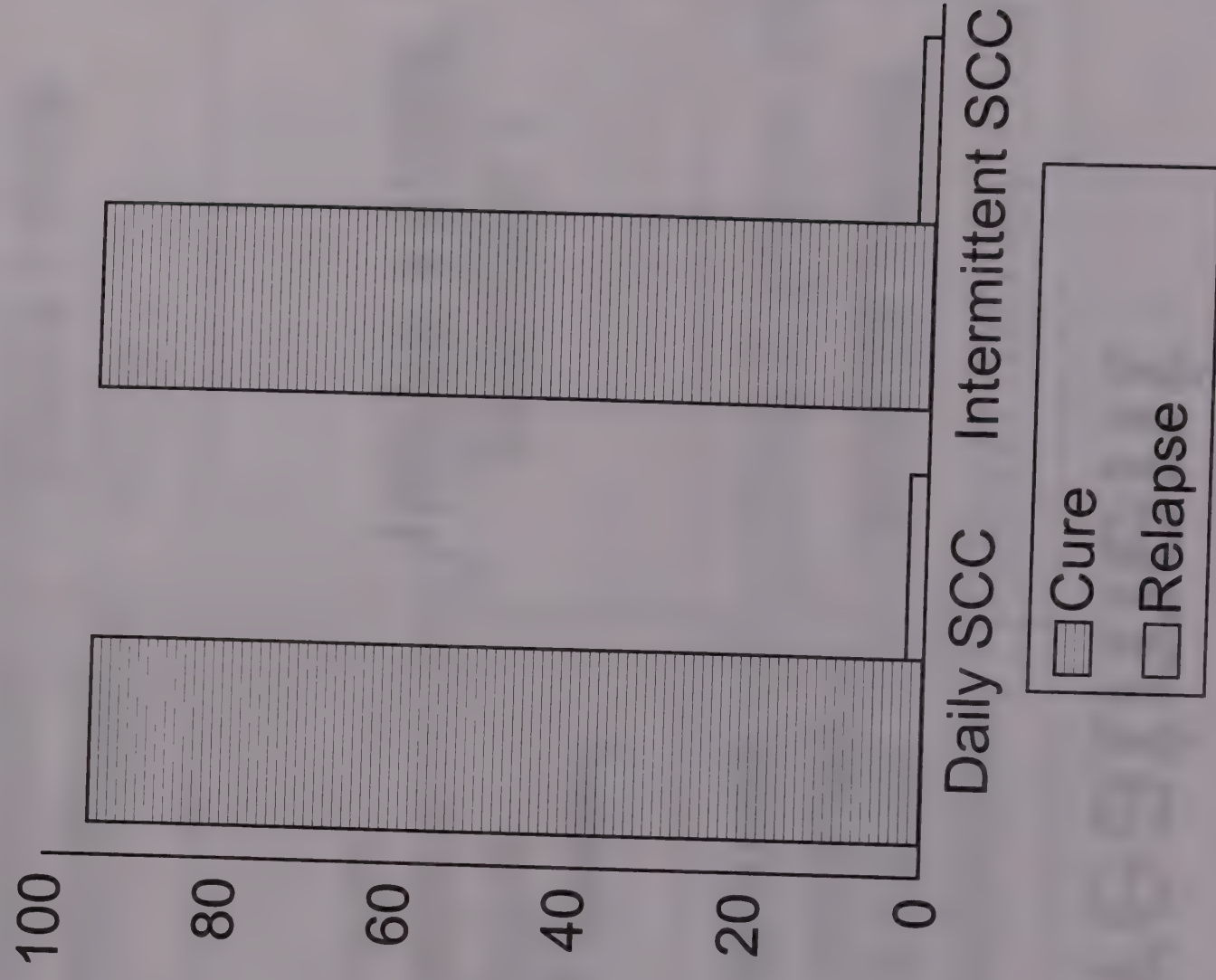
RNTCP Treatment

Category I	New smear-positive; seriously ill smear negative; seriously ill extrapulmonary	2HRZE / 4HR
Category II	Previously treated smear-positive (relapse, failure, treatment after default)	2HRZES / 1HRZE / 5HRE
Category III	New smear-negative and extrapulmonary, not seriously ill	2HRZ / 4HR

All treatment thrice weekly. Cat I and Cat II extended one month if smear+ at end of initial intensive phase

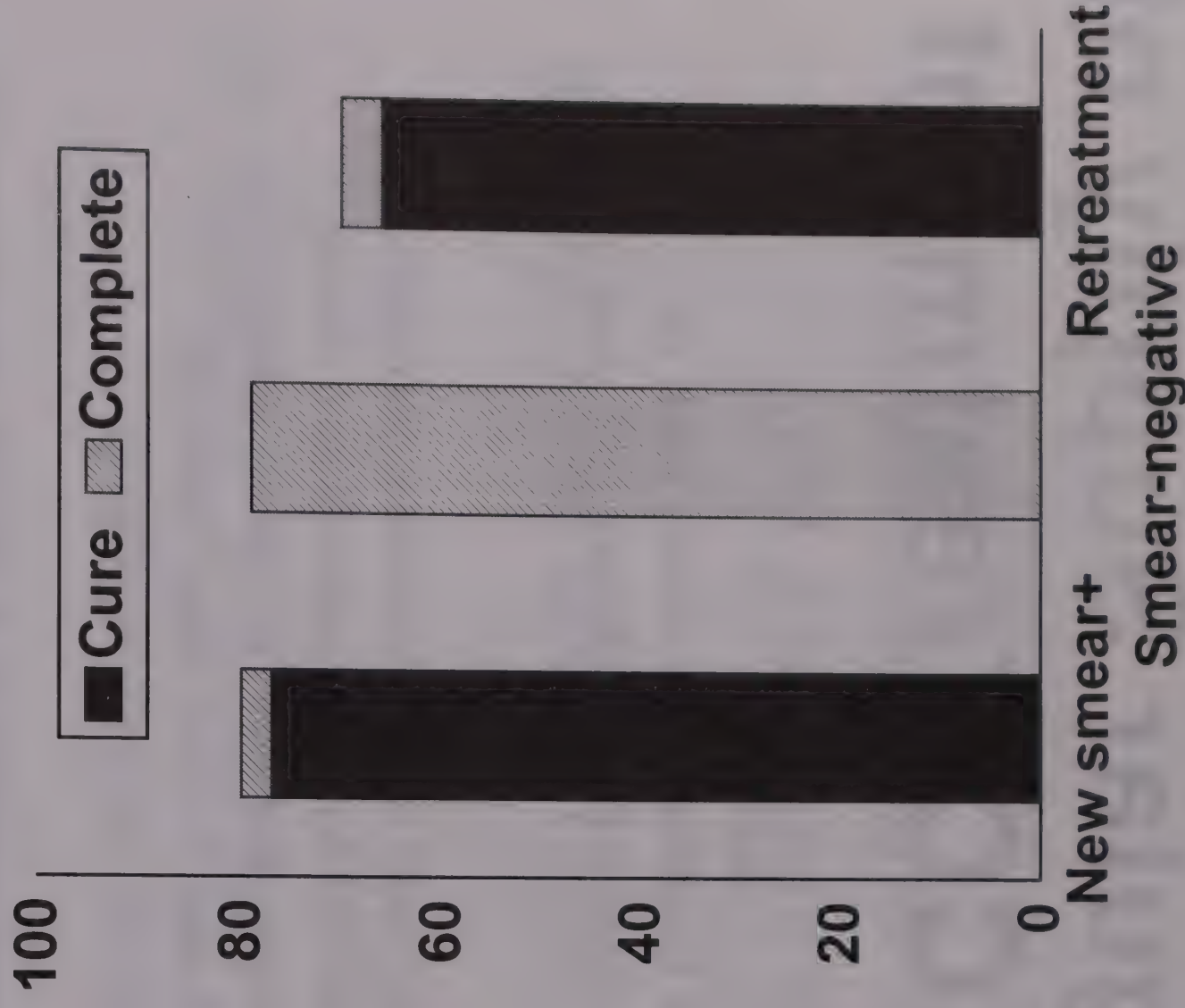
Intermittent Treatment is as Effective as Daily Treatment

- Controlled clinical trials show intermittent treatment to be as effective as daily treatment
- Intermittent treatment has slightly less toxicity than daily treatment
- However, intermittent treatment should only be given in a programme of directly observed treatment



RNTCP Treatment Succeeds Under Programme Conditions for All Types of Patients

- More than 50,000 TB patients put on treatment under RNTCP since 1993
- Outcomes systematically evaluated in every patient placed on treatment
- Of more than 20,000 patients evaluated to date 80% have been cured
- Successful treatment (cure+completion) more than double that of NTP



Exercise 3: Regular Supply of Standardized SCC Treatment

What is the population of your area? _____ lakh
Assuming that 135 patients are placed on treatment for every lakh of population, how many patients would be placed on treatment per year in your area under RNTCP? _____

Under NTP, at most half of patients treated with short-course chemotherapy regimens are cured. Under RNTCP, 8 out of 10 such patients are cured. Thus, at least 30% more patients are cured under RNTCP than under NTP. What is the number of additional patient cured in your area from RNTCP implementation? _____

A patient is smear positive after having been treated by a private physician for 3 months. He should receive treatment with: Cat I Cat II Cat III

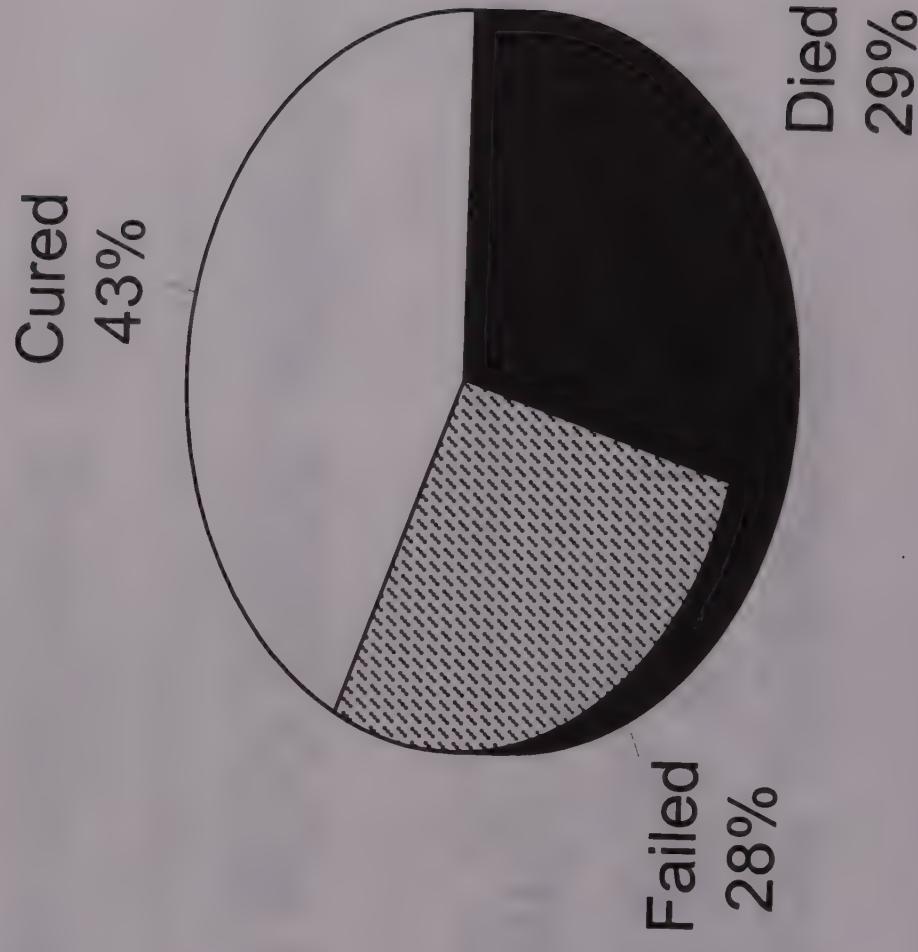
A patient is smear-negative, but has large pleural effusion with respiratory insufficiency. He should receive treatment with: Cat I Cat II Cat III

Direct Observation of Treatment

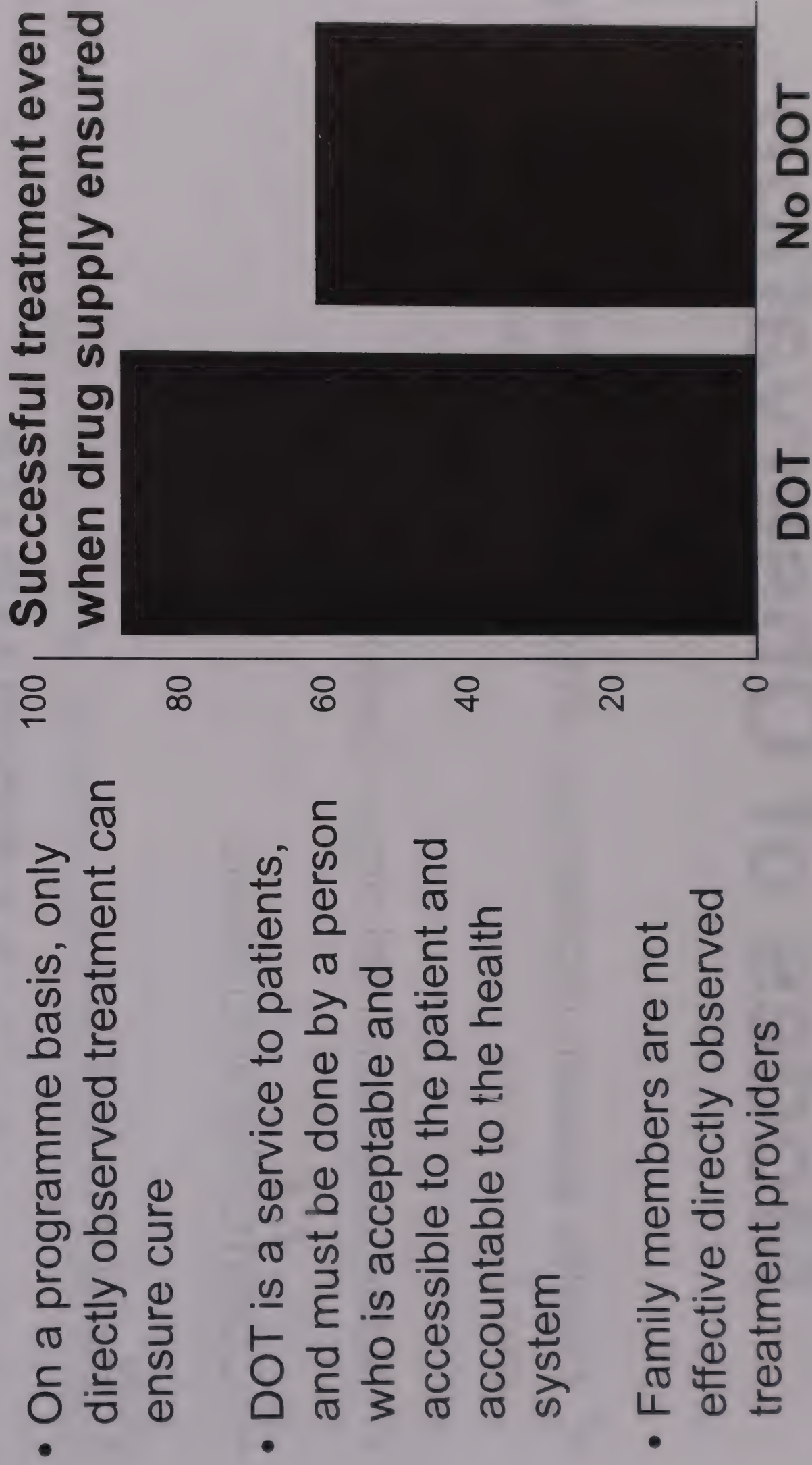
- Multiple studies in India and elsewhere demonstrate that at least one third of patients do not take medicines regularly
- It is impossible to predict who these patients are
- Directly observed anti-TB treatment was discovered in India and is now standard of care internationally, in both developed and developing countries

Uninterrupted Drug Supply is Necessary but Not Sufficient to Ensure Cure

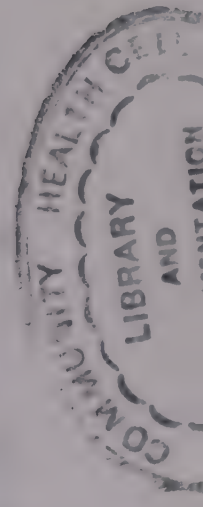
- Evaluation of a well-functioning District Tuberculosis Centre under NTP by the TB Research Centre, Chennai
- Even with regular supply of drugs, nearly one third of patients died, and nearly one third remained sputum positive



DOT Ensures Cure, other Methods do NOT



- On a programme basis, only directly observed treatment can ensure cure
- DOT is a service to patients, and must be done by a person who is acceptable and accessible to the patient and accountable to the health system
- Family members are not effective directly observed treatment providers



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Modes of Observation

- Health system (hospitals, clinics, MPW, ANM, pharmacist, etc.)
- Non-governmental organizations
- Community volunteers
- Religious leaders
- Anganwadi workers, Dais, etc.
- *DOT is feasible in each community by identifying and involving the strengths of the community*

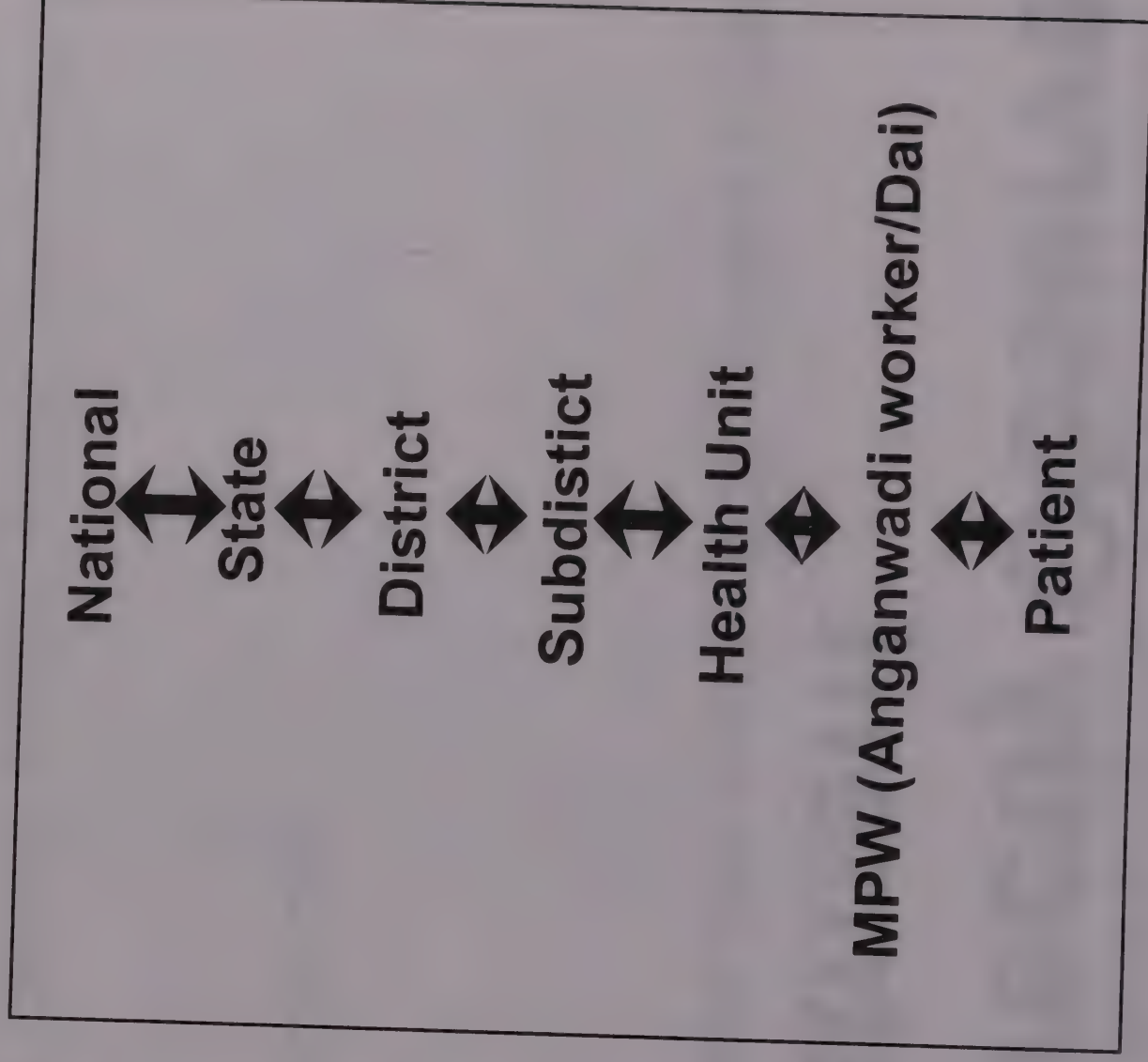
Exercise 4: Directly Observed Treatment

List at least 10 different types of people who could be DOT providers in your area.

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____
8. _____
9. _____
10. _____

RNTCP Ensures Systematic Monitoring, Supervision and Accountability at Every Level

- There is a system of verifiable accountability at every level.
- Each level must do its part to ensure cure of the patient and to break the chain of transmission
- The RNTCP creates a *subdistrict* level (TU) for the exclusive purpose of supervision and monitoring of TB control activities



Sub-district (TB Unit)

- The TB Unit (TU) covers a population of approximately 5 lakhs
- The TU is staffed by of one senior treatment supervisor (STS) and one senior TB laboratory supervisor (STLS)
- These are full-time staff which are new posts exclusively for TB work
- A designated MO supervises the work of the TU in addition to his/her other responsibilities

Key Functions of the TU

- Maintain the *TB Register* which contains information on the diagnosis and treatment of every patient
- Ensure effective diagnosis by microscopy and treatment by directly observed treatment
- Complete quarterly reports on diagnosis, sputum conversion, treatment outcome, and programme management

Quarterly Report on New and Retreatment Cases

- Number and type of patients diagnosed and put on treatment
- Age and sex distribution of cases
- Efficiency of case finding (expect 60 or more new smear-positive cases per lakh per year)
- Quality of diagnosis (expect at least half of pulmonary cases to be smear positive)

Quarterly Report on New and Retreatment Cases

Pulmonary tuberculosis							Extra-pulmonary tuberculosis	
Smear positive					Smear-negative			
New cases			Relapses					
M	F	Total	M	F	M	F		
150	114	264	26	10	125	75	13	25

What is the ratio of smear-positive to smear-negative patients? ___ to ___
 If the population of the area reported on is 10 lakh and 200 new smear-positive cases were reported in each of the four quarters, what would be the annual detection rate (per lakh) of new smear-positive cases? ___

Quarterly Report on Sputum Conversion

- All patients begun on treatment are included in the denominator
- Target is 90% conversion of new smear-positive cases to negative by third month of treatment
- A sputum conversion rate of less than 80% indicates serious problems and a need for intensive supervision

Quarterly Report on Sputum Conversion

Total number of new sputum-positive patients	Sputum at 2 months			Sputum at 3 months		
	Negative	Positive	N.A.	Negative	Positive	N.A.
200	180	10	10	6	1	3

What is the rate of sputum conversion at 2 months? _____%

What is the rate of sputum conversion at 3 months? _____%

Quarterly Report on Treatment Outcome

- The most important measure of programme success
- Expect 85% cure of new smear-positive cases
- Cure rate of less than 80% or default rate of more than 10% indicate a need for intensive supervision

Quarterly Report on Treatment Outcomes

Patients reported during quarter	Type of patient	Cured	Treatment completed	Died	Failure	Defaulted	Transferred to another district	Total number evaluated
200	New smear-positive	170	6	8	2	10	4	200

What is the cure rate? _____%
 What is the completion (cure+treatment completed) rate? _____%
 What is the death rate? _____%
 What is the failure rate? _____%
 What is the default rate? _____%
 What is the default + transfer rate? _____%

Quarterly Report on Programme Management and Logistics

- Monitors and helps in ensuring regular and uninterrupted supply of medicines and laboratory reagents
- Reports number of smears performed, smear positivity rate, initial default rate, and results of quality control testing of sputum
- Helps monitor staffing and training activities

Quarterly Report on Programme Management

Number of chest symptomatic patients whose sputum was examined for case-finding (diagnosis)	(a)	3000
Number of smear-positive patients diagnosed	(b)	300
Of the number of smear-positive patients diagnosed (b), number put on DOTS	(c)	264
Of the number of smear-positive patients diagnosed (b), number put on treatment other than DOTS	(d)	21
Of the number of smear-positive patients diagnosed (b), number not put on treatment (initial defaulters)	(e)	15
Of the above number of initial defaulters (e), number living within the District	(f)	12

What percentage of chest symptomatics were smear-positive? _____ %
 What percentage of smear-positive patients were placed on DOTS? _____ %
 What was the rate of initial defaulters among smear-positive patients living within the District? _____ %

ANSWER KEY

Exercise 1: For 20 lakh population, deaths per year = 1060, per month: 88 per week = 22. Estimated deaths among 18-59 year-old people: 848

Annual loss of productivity from TB deaths: 1060 deaths X 20 years X Rs 10,000/year = Rs 21.2 crore

Deaths averted per year by RNTCP implementation: 530. Economic losses averted by RNTCP implementation: 530 X 20 years X Rs 10,000/year = Rs 10.6 crore.

Exercise 2: Advantages of sputum microscopy: 1. Highly specific -- confirms TB, 2. Correlates with infectiousness, 3. Provides objective means of follow up if initially positive, 4. Low cost, 5. Allows prioritization of smear-positive cases, 6. Can be done effectively in periphery, 7. Correlates with severity of illness and mortality, 8. Appropriate, low-technology, 9. Objective, reproducible, 10. Simple to perform, 11. Minimal infrastructure required, 12. Quick results, etc.

Disadvantages of x-ray as primary tool for diagnosis of tuberculosis: 1. Not standardized or objective -- intra- and inter-observer variability, 2. Many false-positives -- results in overdiagnosis of TB, 3. Does not correlate with infectiousness, 4. Not reliable as an indicator of progress of treatment, 5. Loss of prioritization of patients, 6. Unnecessary treatment, 7. More costly, etc.

Inputs which must be present for microscopy to be effective: 1. Functional microscope, 2. Trained microscopist, 3. Adequate supply of reagents, materials, forms, 4. Regular and effective supervision, 5. Appropriate referral from medical officers, 6. Accurate and prompt registration and reporting of results, etc.

Adverse health effects from lack of microscopy services: 1. Delay in diagnosis leading to more illness and death, 2. Spread of tuberculosis because of delay in starting treatment, 3. Inability to monitor patients on treatment, 4. Inability to determine patient outcome (cured, etc.), 5. Undermine confidence in health system

Exercise 3: For 20 lakh, $20 \times 135 = 2700$ patients would be seen in a year. This would translate into 900 additional patient cures.

A patient who is smear positive after being treated by a private physician for 3 months should receive Category II treatment. A patient who is smear-negative but who is seriously ill should receive Category I treatment. There should be no more than 1-2 of such patients for every 10 smear-positive patients treated.

Exercise 4: Possible DOT providers include MPWs, TBHVs, Anganwadi workers, trained Dais, religious leaders, members of non-governmental organizations, clinic nurses, pharmacists, community volunteers, teachers, etc. The most successful DOT providers are those who are convenient to and trusted by the patient and also accountable to the health system. Family members are NOT effective as DOT providers.

Quarterly Report on New and Retreatment Cases: Ratio is 300:200 or 1.5:1. Annual rate would be 80/lakh/year.

Quarterly Report on Sputum Conversion: Rate at 2 months is 90%. Rate at 3 months is 93%.

Quarterly Report on Treatment Outcomes: cure 85%, completion 88%, death 4%, failure 1%, default 5%, default+transfer 7%.

Quarterly Report on Programme Management: Percentage of chest symptomatics were smear-positive: 10%. Percentage of smear-positive patients placed on DOTS: 88%. Rate of initial defaulters among smear-positive patients living within the District? 4% ($12 \div 300 \times 100$).

TB is a Global

Emergency

BUT

**TB Can be Cured and the
Spread of Disease
Stopped by RNTCP**



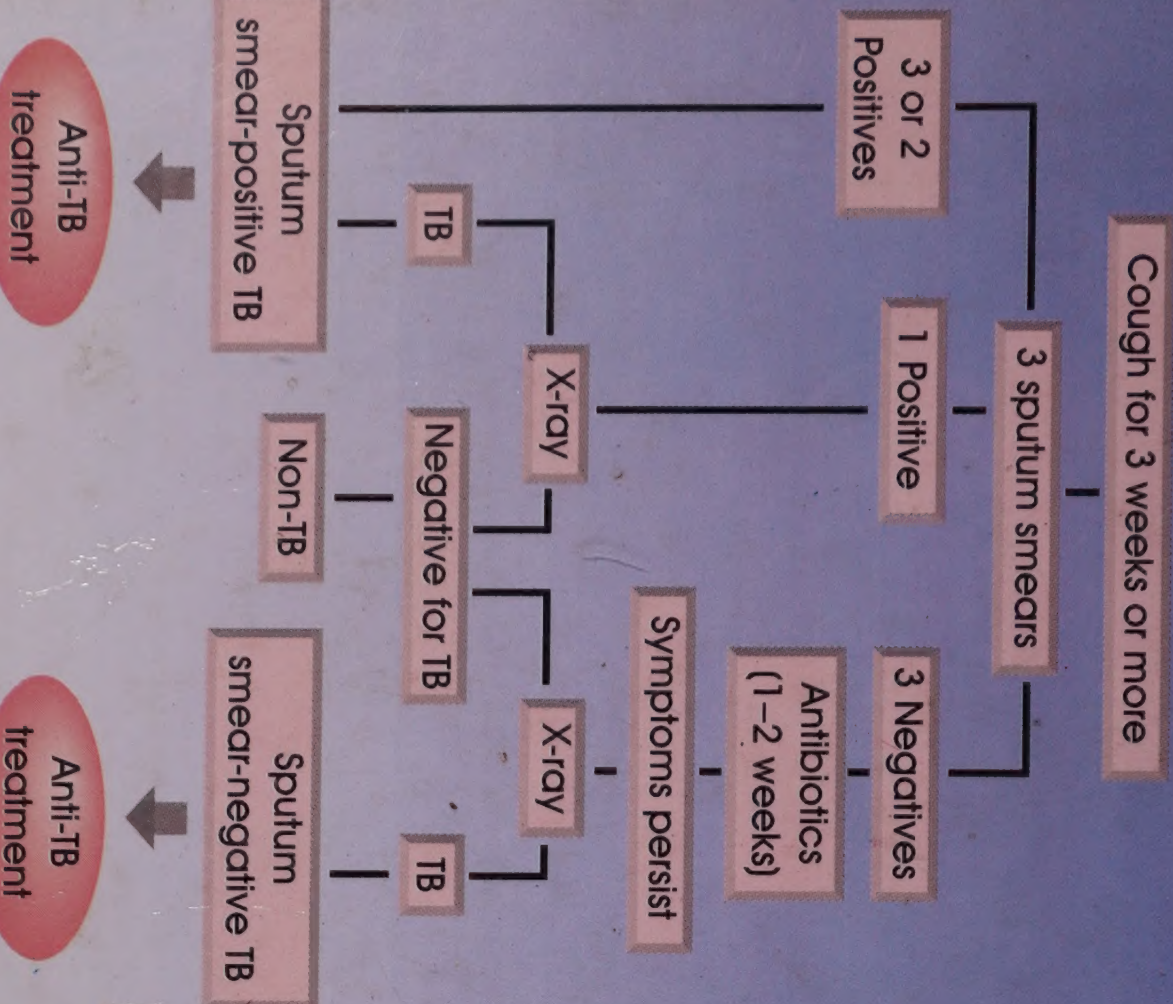
Revised National Tuberculosis Control Programme

CENTRAL TB DIVISION
DIRECTORATE GENERAL OF HEALTH SERVICES
MINISTRY OF HEALTH AND FAMILY WELFARE
NIRMAN BHAVAN, NEW DELHI 110011



DIAGNOSIS

- Ask all patients if they have had cough for 3 weeks or more.
- For all patients with cough for 3 weeks or more, ensure that 3 sputum examinations (spot—morning—spot) are done in a designated microscopy centre.



THE HEALTH SYSTEM—NOT THE PATIENT—IS RESPONSIBLE AND ACCOUNTABLE FOR PATIENT CURE

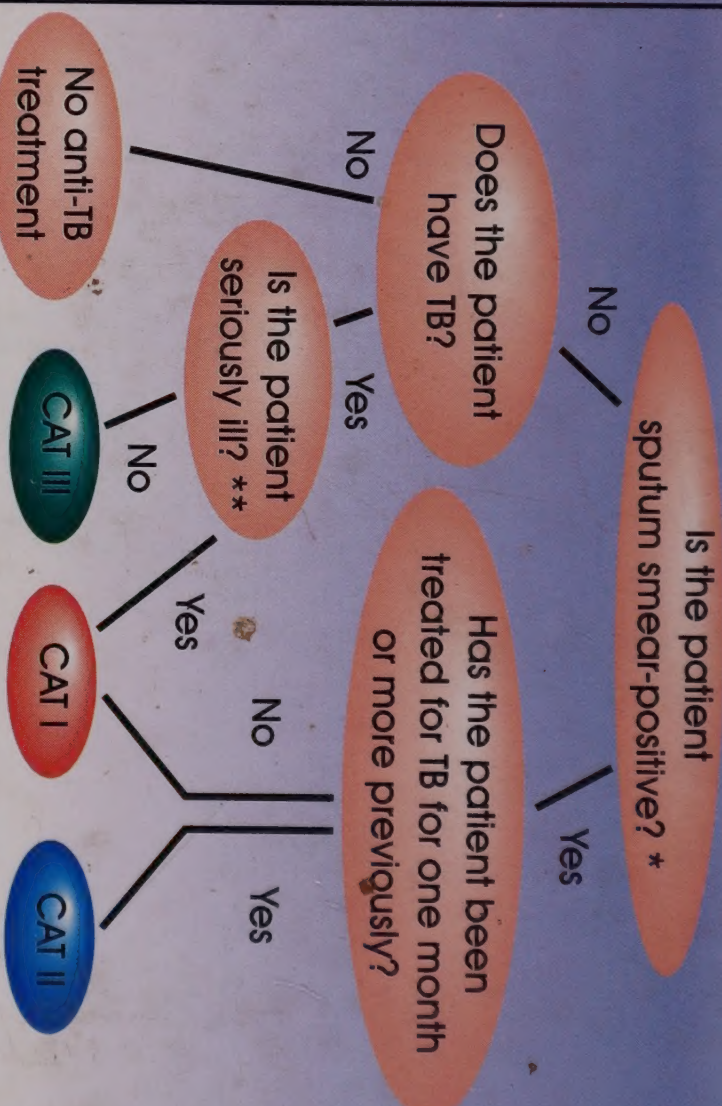
Microscopy is the best way to diagnose pulmonary tuberculosis

Tuberculosis treatment is FREE OF COST at Government Health Facilities

Directly Observed Treatment

A health worker or other trained person who is not a family member watches the patient swallow every dose of medicine in the intensive phase. In the continuation phase, every week at least the first of three doses must be given under direct observation. This is the only way to ensure that the patient is cured.

TREATMENT



* Patients with extra-pulmonary TB should receive Category III treatment unless they are seriously ill, in which case they should receive Category I treatment.

** Examples of seriously ill patients are those suffering from meningitis, disseminated TB, tuberculous pericarditis, peritonitis, bilateral or extensive pleurisy, spinal TB with neurological complications, smear-negative pulmonary TB with extensive parenchymal involvement, intestinal and genitourinary TB.



TREATMENT REGIMEN

SPUTUM EXAMINATIONS

Category of treatment	Type of patient	Regimen [†]	Pre-treatment sputum	Test at month	If result is:	Then
Category I	New sputum smear-positive	2(HRZE) _s	+	2	–	Start continuation phase, test sputum again at 4 and 6 months ^{††}
	Seriously ill sputum smear-negative Seriously ill extra-pulmonary [‡]	4(HR) _s	–	2	–	Continue intensive phase for one more month, test sputum again at 3, 5, and 7 months ^{††}
Category II	Sputum smear-positive Relapse [‡] Sputum smear-positive Failure [‡] Sputum smear-positive Treatment After Default	2(HRZE) _s 1(HRZE) _s 5(HRE) _s	+	3	–	Start continuation phase, test sputum again at 5 and 8 months
	Sputum smear-negative, not seriously ill	2(HRZ) _s 4(HR) _s	–	2	–	Continue intensive phase for one more month, test sputum again at 3, 5, and 7 months ^{††}
Category III	Extra-pulmonary, not seriously ill	2(HRZ) _s 4(HR) _s	–	2	–	Start continuation phase, test sputum again at 4, 6, and 9 months
					+	Re-register the patient and begin Category II treatment afresh

[†] The number before the letters refers to the number of months of treatment. The subscript after the letters refers to the number of doses per week. H: Isoniazid (600 mg), R: Rifampicin (450 mg), Z: Pyrazinamide (1500 mg), E: Ethambutol (1200 mg), S: Streptomycin (750 mg). Patients who weigh more than 60 kg receive additional rifampicin 150 mg. Patients more than 50 years old receive streptomycin 500 mg. Patients in Categories I and II who have a positive sputum smear at the end of the initial intensive phase receive an additional month of intensive phase treatment.

[‡] Examples of seriously ill patients are those suffering from meningitis, disseminated TB, tuberculous pericarditis, peritonitis, bilateral or extensive pleurisy, spinal TB with neurological complications, smear-negative pulmonary TB with extensive parenchymal involvement, intestinal and genitourinary TB.

[§] In rare and exceptional cases, patients who are sputum smear-negative or who have extra-pulmonary disease can have Relapse or Failure. This diagnosis should be supported by culture or histological evidence of active tuberculosis. In these cases, the patient should be registered as 'Other' and given Category II treatment.

^{††} Any patient treated under Category I or Category III who has a positive smear at 5, 6, or 7 months of treatment should be considered a Failure and put on Category II treatment afresh.